

REMARKS/ARGUMENTS

Objection to the Drawings

The Examiner contends that the drawings submitted were not previously presented in a form of a pen and ink sketch showing changes in red ink and that the drawings allegedly do not contain reference signs mentioned in the description of the invention. Upon an indication of allowable subject matter, Applicant will submit drawings with appropriate changes in accordance with the MPEP.

Claims Drawing to Non-Elected Invention

The Examiner contends that amended Claims 1-14, 16, 17, 19, 31-40 and 43-55 are drawn to a non-elected invention and states that a complete reply to a final rejection must include a cancellation of such non-elected claims. Applicant has done so.

Objections Related to "New Matter"

The Examiner contends that the amendments to the claims add new matter that is allegedly not supported by the original disclosure. The Examiner objects to Claim 20's limitation of "means for providing mechanical motion causing said catheter to rotate" and Claim 26's limitation of "mechanical motion generates vibrations effective to disrupt a clot," because, while being present in the specification, "there is not one embodiment where the means for providing mechanical motion is both rotating and causing vibrations." Moreover, with respect to Claim 41, the Examiner contends that "there is also not one embodiment in the specification where motion is caused by rotation of the catheter and delivery of a lytic agent. These are all separate embodiments and the combination of the embodiments added to the claims constitute new matter."

Applicant respectfully traverses the Examiner's objection to alleged new matter being added by amendments of the claims. While Applicant disagrees with the Examiner's characterization as set forth in the final Office Action, Applicant has attempted to amend the claims in an effort to overcome the Examiner's concerns. Support for the claims can be found in the specification,

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particularly at pages 12-13 where the paragraph specifies not only a spiral shaped catheter, but one that is moved due to pulsations of lytic agents being pumped into the catheter. See also, page 5, last paragraph; page 6, first and second paragraphs; page 9, first paragraph; page 10, last paragraph, etc. If the Examiner believes that such amendments to the claims do not overcome the stated “new matter” objection, Applicant’s counsel requests the courtesy of a telephone call to address such issues and can be reached directly at (303) 863-2977.

Rejections of Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner rejects Claims 26, 41, and 42 under § 112, first paragraph, for “new matter” reasons with respect to the objection to new matter as related above. Applicant has amended such claims in a fashion that is believed to overcome the Examiner’s concerns and as such, requests the Examiner’s favorable consideration of such amended claims and the withdrawal of any §112 rejections thereto.

Rejection of Claims 41 and 42 Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects Claims 41 and 42 as lacking a sufficient antecedent basis for the limitation “said pump.” Applicant has amended Claim 41 in order to cure the antecedent basis problem and therefore requests the Examiner’s withdrawal of the §112, second paragraph, rejection of such claims.

Rejection of Claims Under 35 U.S.C. § 102

The Examiner rejects Claims 20-30 as being anticipated by Auth. The Examiner contends that Auth discloses a catheter having a corkscrew configuration which rotates once inserted within a patient and that breaks up a clot but does not cut or damage the blood vessels (col. 6, lines 37-39, col. 7, lines 11-13). The Examiner also contends that the Auth device is capable of running for prolonged periods of time – if the motor is turned on for 24 hours, then the catheter will run for 24 hours. The Examiner further contends that the intermittent operation referred to in the claims can be met by Auth by merely turning on or off the motor. The Examiner states that Auth discloses a

motor connected to a tip that rotates over an allegedly substantial length. Finally, the Examiner contends that Auth reference numeral 24 can be used to inject chemicals which dissolve emboli and that tip 7 can be used as an occluding device which would hold the fluid coming out of tip 23 in place. Applicant traverses the Examiner's rejection of Claims 20-30 for the reasons as set forth below. To constitute anticipation, all material elements of the claim must be found in one prior art source. *In re Marshall*, 198 USPQ 344 (CCPA 1978); *In re Kalm*, 154 USPQ 10 (CCPA 1967). Auth, especially in view of the amended claims, cannot be relied upon as an anticipatory reference. Moreover, although the Examiner has not made any rejection of the present claims under §103, Applicant does not believe that any of the claims, as presently presented, could be properly rejected on the basis of 35 U.S.C. §103.

At the outset, Applicant acknowledges with appreciation the Examiner's apparent favorable consideration of prior arguments that distinguished the Craig et al. and Monetti references, which were the prior basis for the rejection of pending claims. The Examiner now rejects the amended claims under a new reference which Applicant has not previously had an opportunity to review, the Auth reference, and the Examiner makes the present action "final." If deemed necessary, Applicant respectfully requests the reconsideration and withdrawal of the "finality" of the present Office Action so that the new Auth reference can be adequately distinguished.

Pursuant to MPEP 706.07(c), Applicant respectfully submits that the final rejection in the present case is premature and therefore requests that the Examiner reconsider and withdraw such finality in order that the present prosecution can properly proceed. Applicant herein presents new facts and reasons which are believed to be sufficient to convince the Examiner that the previously rejected claims are in fact allowable and as such, the final rejection should be withdrawn. Alternatively, if the Examiner concedes that the §102 rejection has been overcome, the finality of the rejection should be withdrawn in order to permit Applicant to properly argue any obviousness rejections that the Examiner may present. MPEP 706.07(e) explicitly provides that it is permissible to withdraw a final rejection in situations where a new reference is relied upon to reject claims, (such as the Auth reference as newly cited by the Examiner in this case). The Examiner's admission that the previous prior art used to reject claims has been rendered moot by previous amendments and

arguments, supports such a removal of finality. In any event, Applicant believes that the present case can be expeditiously placed into a condition for allowance by a telephone conference with Applicant's counsel in the event there are any existing issues with respect to the pending claims.

A fair reading of Auth clearly reveals that Auth teaches the use of a catheter solely as a conduit through which a rotating wire can be provided, and the mechanical action disclosed by Auth comes solely from a cutting head which rotates at high speed, such cutting head being separate and apart from the catheter itself. In contrast, one embodiment of the present invention relies upon a corkscrew-shaped catheter wherein the catheter itself rotates to provide the mechanical movement that disrupts clots in veins and arteries.

Although the Examiner has not yet formally made a §103 rejection of any claims (and in an attempt to avoid a further Office Action on such basis), Applicant provides arguments with respect to any obviousness concerns that the Examiner may contemplate.

With respect to Auth, Applicant respectfully notes that Auth is directed to a device having a rotating cutting tool that rotates at greater than 2,000 rpm. The rotation is so forceful that it tends to force blood into ports that extend in front of a cutting flute. The alleged "corkscrew" configuration shown in Auth is merely the cutting tool 1, which is connected to a drive shaft 2, which itself extends through a guiding catheter 3. As such, it is clear that the catheter itself that is used by Auth does not rotate, but rather it is merely the cutting tool head of Auth that rotates, and at a considerable rotational speed. In contrast, the present invention is directed to a device where the mechanical motion is provided by the catheter itself, rather than a cutting tool at the end of a catheter. The mechanical disruption of a clot is achieved by the rotation of the corkscrew-shaped catheter, not by a cutting head, as disclosed by Auth. Moreover, as amended, the claims dictate a rotation of far less than the rotation contemplated as a minimum amount in the Auth device and method. For these reasons, Auth is not considered to be an anticipatory reference, nor a reference that can be utilized as § 103 prior art (see discussion below).

The Examiner seems in essence to be stating that it would have been “obvious to try” modifying various parameters, and indeed selecting entirely different components and combinations having distinct identifying characteristics, in order to produce the claimed invention. The Federal Circuit has provided clear direction with respect to arguments based on an “obvious to try” theory. The court has held that an “obvious to try” situation exists when a general disclosure may pique a scientists curiosity, such that further investigation might be done as the result of a disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 14 USPQ 2d 1741, 1743 (Fed.Cir. 1990). The court held that “obvious to try” is not to be equated with obviousness under 35 U.S.C. §103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ 2d 1923, 1928 (Fed.Cir. 1990).

In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references “must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention”. *Akzo N.V. v. United States Int’l Trade Commission*, 1 USPQ2d 1241 (Fed. Cir. 1986) *cert denied*, U.S. 909 (1987); *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593 (Fed. Cir.), *cert denied*, 481 U.S. 1052 (1987).

A simple invention may be patentable, even if the invention comprises a combination of features known in the art, provided the combination itself is not obvious. See *In re Dembiczak*, 50 USPQ 2d 1614, 1617 (Fed. Cir. 1999); *In re Dance*, 48 USPQ 2d 1635, 1637 (Fed. Cir. 1998); *In re Kotzab*, 55 USPQ 2d 1313, 1317 (Fed. Cir. 2000). *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969) (“A patentable invention, within the ambit of 35 U.S.C. §103, may result even if the inventor has, in effect, merely combined features, old in the art, for their known purpose, without producing anything beyond the results inherent in their use.”) (emphasis omitted). It is insufficient that the prior art merely discloses the components of a patented invention, either separately or used in other combinations - there must be some teaching, suggestion or incentive to make the combination made by the inventor. *Northern Telecom v. Datapoint Corporation*, 908 F.2d 931, 934, 15 USPQ 2d 1321, 1323 (Fed. Cir. 1990); *Uniroyal, Inc. v. Rudkin-Wiley Corporation*, 837 F.2d 1044, 1051, 5 USPQ 1434, 1438 (Fed. Cir. 1988). That knowledge may have been within

the province of the ordinary artisan does not in and of itself make itself obvious absent clear and convincing evidence of such knowledge. *See C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 58 USPQ 2d 1225, 1232 (Fed. Cir. 1998). Care must be taken to avoid hindsight reconstruction while using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. *Grain Processing Corp. v. American Maize Products Company*, 840 F.2d 902, 907, 5 USPQ 2d 1788, 1792 (Fed. Cir. 1988); *In re Spinnoble*, 405 F.2d 578, 160 USPQ 237, 243 (CCPA 1969) (A patentable invention, within the ambit of 35 U.S.C. §103, may result even if the inventor has, in effect, merely combined features, old in the art, for their known purpose, without producing anything beyond the results inherent in their use.) (emphasis omitted).

A determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination."). *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 935, 15 USPQ2d 1321, 1324 (Fed. Cir. 1990) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed composition). The motivating suggestion must also be explicit. *Winner International Royalty Corporation v. Wang*, 48 USPQ2d 1139 (D.C., D.C. 1998) ("there must have been some explicit teaching or suggestion in the art to motivate one of even ordinary skill to combine such elements so as to create the same invention"). *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 934, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990) (it is insufficient that prior art shows similar components, unless it also contains some teaching, suggestion, or incentive for arriving at the claimed structure); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051-52, 5 USPQ2d 1434,

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1438 (Fed. Cir. 1988) (it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (it is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor); *Fromsom v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985) (the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

"The mere fact that the prior art may be modified in the manner suggested does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). That individual elements of the inventions are old and can be found in the prior art is irrelevant. *Grain Processing Corp. v. American Maize Products Co.*, 5 USPQ2d 1788 (Fed. Cir. 1988). One cannot pick and choose individual elements from multiple references to recreate the invention. *Polaroid Corp. v. Eastman Kodak Co.*, 229 USPQ 561 (Fed. Cir.), cert. denied, 479 U.S. 850 (1996). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention". *Akzo N.V. v. United States Int'l Trade Commission*, 1 USPQ2d 1241 (Fed. Cir. 1986) cert denied, U.S. 909 (1987); *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593 (Fed. Cir.), cert denied, 481 U.S. 1052 (1987).

In view of this well established case law, Applicant respectfully submits that none of the prior art discloses, teaches or suggests the presently claimed invention.

In her Advisory Action dated June 2, 2003, the Examiner indicated that the proposed amendments would raise new issues that would require further consideration. Applicant respectfully disagrees for the reasons as set forth herein. First, Claim 20 was previously amended to clarify that the catheter itself (rather than any type of cutting head) has a corkscrew configuration throughout its length. This feature alone is sufficient to distinguish the present invention from any of the prior art, and in particular, the teachings of Auth. Auth merely teaches a cutting head having a rather typical spiral drill bit design. Auth fails to teach that the catheter itself has a corkscrew configuration and that it is the catheter itself that rotates. Indeed, Auth teaches away from the present invention in this regard since Auth utilizes a conventional catheter that does not rotate, but rather, merely provides a drive shaft 2 surrounded by a guiding catheter 3. Auth teaches the use of a cutting tool 1, which rotates at extremely high speeds (greater than 25,000 rpm) (see col. 7, line 10). In contrast, the present corkscrew catheter configuration is caused to rotate at far slower speeds.

The Examiner contends that the limitation of rpms raises a "new issue". Applicant respectfully disagrees. Rpm limitations were present in the application as originally filed; prior art searches conducted by both the Applicant and the Patent Office were specifically directed to rpm limitations; and the prior Examiner in this case explicitly discussed prior art where rotational speeds of 500 rpm's were utilized (see Monetti reference and Office Action dated 7/18/02, p. 6, ¶19).

In any event, Applicant respectfully contends that the corkscrew configuration throughout the length of the catheter as claimed in the present invention, is neither disclosed nor taught or suggested by any one or a combination of prior art references. There has been extensive examination in searching of the prior art with respect to the invention as claimed and the suggested claim amendments as proposed in the Amendment After Final dated 5/20/03 do not raise new issues or add "new matter" that would require additional searching. Moreover, the previously amended Claim 20 (as presented in the Amendment and Response filed 12/18/02), presented the corkscrew catheter configuration so that even if the suggested amendments to the claims as proposed on 5/20/03 are not accepted, Claim 20 as previously presented is patentable over and above the prior art of record.

Applicant's counsel requests the courtesy of a telephone interview with the Examiner in the event that the previously amended claims are not believed to be in a condition for allowance or if



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any other suggested Examiner's amendments may place the same in a condition for allowance.  
Applicant's counsel can be reached directly at (303) 863-2977.

Respectfully submitted,

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